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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/817,015 | 03/23/2001 | Willem P.C. Stemmer | 02-104720US | 5728 |

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MAXYGEN, INC.
INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER

FRIEND, TOMAS H F

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1639

DATE MAILED: 05/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/817,015

Applicant(s)

STEMMER ET AL.

Examiner

Tomas Friend

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-185 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-185 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Status of the Application

Receipt is acknowledged of information disclosure statements on 20 July 2001, 03 December 2001, and 29 January 2002 (Paper Nos. 4-6).

Status of the Claims

Claims 1-185 are pending in the present application and are subject to restriction and election of species requirements.

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-40, drawn to a method for controlling a phenotype comprising providing a population of conjoint polynucleotide segments, classified in class 435, digest 17.
- II. Claims 41-73, drawn to a method for controlling a phenotype comprising providing a library of nucleic acids, classified in class 514, subclass 44.
- III. Claims 74-108, drawn to a method of controlling a complex phenotype, classified in class 514, subclass 44.
- IV. Claims 109-153, drawn to a method of modulating activity of one or more targets, classified in class 514, subclass 2.
- V. Claims 154-166, drawn to a method of producing a library of pre-selected peptides, classified in class 435, digest 47.

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- VI. Claim 167, drawn to a library of pre-selected peptide, classified in class 530 and one of numerous subclasses depending on the lengths and sequences of the peptides.
- VII. Claims 168-172, drawn to a library of nucleic acids, classified in class 536, subclass 24.5.
- VIII. Claims 173-176, drawn to a library of conjoint polynucleotide segments, classified in class 536, subclass 23.4.
- IX. Claims 177-180, drawn to a library of recombinant concatamers, classified in class 536, subclass 23.1.
- X. Claims 181-182, drawn to a vector, classified in class 435, subclass 320.1.
- XI. Claims 183-185, drawn to a cell or organism, classified in class 435 and one of numerous subclasses, depending on the cell or organism.

The inventions are distinct, each from the other because:

Inventions VI and XI and Inventions I-III and V are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the composition of Invention XI can be made by any of the processes of Inventions I, II, or III. The composition of Invention VI can be made by the method of Invention V or, alternatively, can be made by chemical synthesis, for example.

Inventions VII-X and Inventions I, II, and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compositions of Inventions VII-X are used in any of Inventions I, II, or IV.

Inventions I-V are different and patentably distinct methods because they involve different method steps, starting materials, reagents, and/or reaction conditions and/or produce

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different products or results. For example, the methods of Inventions I and II are methods for controlling a phenotype, while the methods of Inventions III-V are methods of controlling a complex phenotype, modulating the activity of one or more targets, and producing a library of pre-selected peptides, respectively. The method of Invention I requires, for example, a recombining or mutating step not found in the methods of Inventions II and III. The method of Invention III does not require conjoint polynucleotide sequences and does require subsets of two or more members of a library of nucleic acids to alter expression or activity of one or more components of a multigenic phenotype unlike the methods of Inventions I and II.

Inventions VI-XI are different and patentably distinct compositions because they have different chemical and/or biological structures with different chemical, biological, and physical properties. For example the compositions of Invention VI is a peptide, while the compositions of Inventions VII-XI are not. The composition of Invention XI is a cell or organism, while the compositions of Inventions VII-X are not. The composition of Invention X is a vector, while the compositions of Inventions VII-IX are not. The library of recombinant concatamers of Invention IX is made from the library of conjoint polynucleotide segments of Invention VIII, while the library of nucleic acids of Invention VII are operably linked to at least one transcription regulatory sequence, unlike the concatamers of Invention VIII.

Because these inventions are distinct for the reasons given above and

- a. have acquired a separate status in the art as shown by their different classification ;
- b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
- c. have divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under CFR 1.17(h).

Election/Restriction

The composition claims lack any identifiable structural and/or functional characteristics that would make a search of the prior art possible. The method claims, including compositions, their use in or production by the claimed methods, and the method steps, lack sufficient structural and functionally cooperative relationships that would allow a meaningful search of the prior art. Accordingly, the following additional election/restriction requirement is necessary.

This application contains claims directed to patentably distinct species of the claimed invention. If applicant elects any of Inventions I-III, X, or XI, applicant is required to elect a species for each of the following A-G.

- A. ultimate species of phenotype (exactly what phenotype is being controlled), and ultimate species of desired phenotype, if different from the phenotype to be controlled,
- B. species of conjoint polynucleotides segments (i.e. comprise, encode, or modulate the phenotype elected in A),
- C. ultimate species of population into which concatamers are introduced (i.e. exactly what cell type or organelle within a particular cell type),
- D. species of identifying the ultimate species of C (e.g. from those recited in claims 8-13),
- E. species of conjoint polynucleotide segments (e.g. from the list in claim 19 and including the species of vector, if present),
- F. ultimate species of transcriptional regulatory sequence (Inventions II and III), AND
- G. species of identifying preselected polynucleotide segments (Inventions II and III, e.g. from claims 49-54 or 80-85).

If applicant elects Inventions IV, applicant is required to elect a species for each of the following A-F.

- A. ultimate species of desired property(ies) (i.e. the number of different properties and exactly what they are),
- B. ultimate species of transcriptional regulatory sequence(s),

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- C. ultimate species of target(s) (specify a molecular target(s))
- D. species of modulating C (e.g. from list in claim 137)
- E. species of recipient cell (claim 121), AND
- F. species of identifying preselected polynucleotide segments (e.g. from among claims 125-131).

If applicant elects Invention V or VI, applicant is required to elect a species for each of the following A-C.

- A. species of displaying peptide moiety (e.g. from claims 161 and 162),
- B. species of identifying a plurality of variable peptide moieties (method(s) used), AND
- C. ultimate species of desired property.

If applicant elects Invention VII, applicant is required to elect a species for each of the following A and B.

- A. species of endogenous phenotype AND
- B. species of component(s) of A.

If applicant elects any of Inventions VIII or IX, applicant is required to elect a species for each of the following A and B.

- A. species of recombinant concatamers (e.g. from lists in claims 174 and 178), AND
- B. species of sequences present in A (from lists in claims 175 and 179).

The species are distinct, each from the other, because they have different structures with different chemical, physical, and/or biological properties. Therefore, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

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thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).


Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend**, telephone number **(703) 308-4548**. The examiner's schedule is normally four, ten-hour days per week that includes Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.
12 May 2003



ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600